

Claims

1. A trans-luminal, guidewire-advanced, rapid-exchange surgical delivery device having a proximal end, a primary shaft and a distal zone to be advanced over the guidewire along a bodily lumen to a site of surgery; and

characterised by:

- i. tubular means for a guidewire and for defining a guidewire lumen, said tubular means lying within the distal zone with the guidewire lumen to one side of the primary shaft and having a proximal end opening which lies to one side of the shaft;
- ii. sleeve-shaped means for defining a lumen to receive a surgical element distal of the tubular means, the sleeve-shaped means having a proximal end which is form-fitted over the primary shaft and has a radially inwardly tapering portion proximal of the proximal end of the tubular means, said inwardly tapering portion defining a proximal guidewire lumen exit port.

2. Device as claimed in claim 1, characterised in that said primary shaft is a tube.

3. Device as claimed in claim 2, characterised in that said tube contains an inner shaft which, in use, may slide relative to the tube, whereby the imposition of endwise compression on the inner shaft and endwise tension on the tube may withdraw the sleeve proximally relative to the distal end of the inner shaft.

4. Device as claimed in claim 3 wherein the distal end of the inner shaft is configured as a pusher, to maintain the position of said surgical element at said site of surgery during proximal withdrawal of the sleeve to expose the surgical element to the bodily lumen.

5. Device as claimed in claim 4 including the surgical element.

6. Device as claimed in claim 5 wherein the surgical element is a self-expanding stent.

7. Device as claimed in any one of the preceding claims wherein the sleeve is reinforced by filamentary material within its wall thickness.

8. Device as claimed in claim 7 wherein the filamentary material is braided material.

9. Device as claimed in claim 7 or 8 wherein the filamentary material stops distally short of the distal end of the sleeve.

10. Device as claimed in any one of the preceding claims wherein the distal end of the sleeve is tapered inwardly to provide the device, at least prior to its arrival at the site of surgery, with a more or less atraumatic tip.

11. Device as claimed in any one of the preceding claims wherein the proximal end of the sleeve is form-fitted by the application of heat and radially inward pressure.

12. Device as claimed in any one of the preceding claims wherein the sleeve includes a push zone through which an endwise compression force imposed on the proximal end of the primary shaft can be transferred to the sleeve for advancing the sleeve along the bodily lumen to the site of surgery.

13. Device as claimed in claim 12 wherein the push zone corresponds to an annulus in which the sleeve has a reduced outside diameter relative to its diameter immediately proximal of said push zone.

14. Device as claimed in claim 12 or 13 wherein the push zone corresponds to an annulus in which the sleeve has a reduced inside diameter relative to its inside diameter immediately proximal of said push zone.

15. Device as claimed in claim 12, 13 or 14 wherein the push one is found immediately distal of the distal end of the primary shaft.

16. Device as claimed in any one of the preceding claims wherein the guider tube extends distally beyond the distal end of the primary shaft.

17. Device as claimed in any one of the preceding claims and including a guidewire guider hose having a proximal end and a distal end, said proximal end being contiguous with the distal end of the guider tube.

18. Device as claimed in claim 17 wherein the distal end of the guider hose is flared radially outwardly, towards the luminal wall of the sleeve.

19. Device as claimed in claim 18 as dependent on claim 3, or any of claims 4 to 16 as dependent on claim 3, wherein the inner shaft extends distally beyond the distal end of the guider hose, along a path between the abluminal wall of the guider hose and the luminal wall of the sleeve.

20. Device as claimed in claim 19 wherein the distal end of the inner shaft carries an annular surgical element pusher which defines a portion of the length of the guidewire lumen which is aligned with the lumen for the guidewire beyond the distal end of the guider hose.

21. Device as claimed in claim 20 wherein the annular pusher carries a carrier tube which extends distally from the

annular pusher and itself defines a portion of the length of the guidewire lumen.

22. Device as claimed in claim 21 wherein the carrier tube carries a radiopaque marker band at or near its distal end.

23. Device as claimed in claim 21 or 22 wherein the carrier tube extends proximally from the annular pusher sufficiently far to define a portion which tapers outwardly towards the luminal wall of the sleeve, for guiding into the carrier tube the distal end of a guidewire advanced through the guidewire lumen distally, from the proximal exit port.

24. Device as claimed in any one of claims 19 to 23, wherein the inner shaft includes a connector, located axially between the distal end of the primary shaft and the annular pusher, said connector permitting adjustment of the axial position of the annular pusher relative to the distal end of the sleeve, during assembly of the device, to cater for different lengths of the surgical element.

25. Device as claimed in claim 24 wherein the inner shaft comprises a distal portion of solid cross-section and a proximal tubular portion, the tubular portion extending within the primary tube shaft and distally therefrom, to said connector, or to a point proximal of said connector.

26. Device as claimed in claim 25 wherein the inner shaft exhibits an unbroken metal strand as far as the annular pusher

27. Device as claimed in claim 1, in which the sleeve can be withdrawn proximally to release a self-expanding implant and which includes

a stopper to prevent proximal movement of the implant when the sleeve moves proximally, and wherein the primary shaft exhibits

a pull wire for pulling back the sleeve and  
a shaft tube with a lumen containing the pull wire  
and with a distal end operatively connected to the stopper.

28. Device as claimed in claim 27, wherein the shaft tube is a stainless steel or cobalt alloy hypo tube.

29. Device as claimed in claim 27 or 28, wherein the pull wire is of metal.

30. Device as claimed in any one of the preceding claims 27 to 29, wherein the sleeve is of polymer with fiber reinforcement within the polymer wall thickness.

31. Device as claimed in claim 30, wherein said reinforcement fibers are braided metal strands.

32. Device as claimed in any one of claims 27 to 31, wherein the pull wire is connected to the sleeve by first and second coaxial metal rings, one radially inside the sleeve and the other radially outside the sleeve.

33. Device as claimed in claim 32, wherein the metal ring outside the sleeve is swaged down onto the sleeve.

34. Device as claimed in any one of claims 27 to 33, wherein the sleeve has an inwardly tapered distal tip.

35. Device as claimed in any one of claims 27 to 34, and including a collar having a peripheral surface and first and second lumens, wherein

i) the shaft tube is slidably received in the first lumen

ii) the second lumen is said guidewire lumen; and

iii) the peripheral surface carries the proximal end of the sheath

with the collar sliding proximally along the shaft tube during proximal withdrawal of the sleeve.

36. Device as claimed in any one of the preceding claims 27 to 35 and including a pusher tube which defines a lumen through which a guidewire may be advanced, which carries said stopper, and which is bonded at its proximal end to one side of the distal end of the shaft tube.

37. Device as claimed in claim 36, further including a pusher tube extension which continues the lumen of the pusher tube, distal of the stopper, distally to the region of the distal tip of the sleeve.

38. Catheter device as claimed in claim 37, wherein the pusher tube extension carries a distal radiopaque marker band.

39. Catheter device as claimed in any one of the preceding claims, wherein the guider tube is a shaped element of polymer.

40. Catheter device as claimed in any one of the preceding claims, wherein the guider tube is a shaped element that includes a lumen to receive the distal end of the primary shaft.

41. Catheter device as claimed in claim 40, wherein the primary shaft is fixed in the receiving lumen of the guider tube against relative axial movement.

42. Catheter device as claimed in claim 41, wherein the guider tube is of metal and has a protuberance over which the sleeve is form-fitted.

43. Catheter device as claimed in claim 41 in which the guider tube is of polymer, and the sleeve is fused to the guider tube.